UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: MEDTRONIC, INC. IMPLANTABLE DEFIBRILLATORS PRODUCTS LIABILITY LITIGATION	MDL No. 05-1726 (JMR/AJB)
This Document Relates to All Actions	

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' OBJECTIONS TO THE MAGISTRATE JUDGE'S ORDER DATED MARCH 24, 2006

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INTRODUCTION

Although Magistrate Judge Boylan's March 24, 2006 Order (the "Order") recognizes limited pre-emption related discovery, it unduly restricts Plaintiffs' ability to defend against Medtronic's summary judgment motion. As a result, and even though Plaintiffs believe that preemption should be decided on a complete record, Plaintiffs now appeal only the Order as it relates to three very specific and limited document requests: Document Request Nos. 2, 8, and 36.[1] Specifically, Plaintiffs object to the Order to the extent that it does not allow discovery about Medtronic's awareness of the recalled defibrillators' defects and risks, and whether the devices contain design and/or manufacturing defects.

Plaintiffs assert that the Order, as it relates to those requests, is clearly erroneous and contrary to law because: (1) Plaintiffs must support their position that their claims cannot be preempted with *evidence*; and (2) preemption discovery properly includes evidence in support of non-preempted claims (such as

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[1] Request 2 asks for, "Any and all documents relating to customer, patient, and physician complaints, component rejections, and returned devices or device components."

Request 8 asks for, "All product complaint forms and component or product field reports for implanted and/or explanted ICD and CRT-D devices, including reports in the medical literature regarding ICD and CRT-D device failure or malfunction."

Request No. 36 asks for, "Documents regarding design, manufacture and quality assurance of batteries and capacitors of ICDs and/or CRT-Ds." Request No. 36 specifically includes all filed medical device reports and subsequent failure investigation files.

manufacturing defects and other state-law causes of action that parallel federal safety requirements).

Although Plaintiffs generally acknowledge that federal law preempts "fraud-on-the-FDA" claims, *see Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), Plaintiffs strongly disagree that their state-law causes of action (which are rooted in negligence, strict liability, breach of warranty and design or manufacturing defect claims) fall into disguised fraud-on-the-FDA claims, as Medtronic would lead this Court to believe. Medtronic's mischaracterization of Plaintiffs' personal injury claims - as claims secretly designed to police fraud against the FDA - demonstrates its attempt to sidestep controlling law that clearly states that federal law does not preempt state or local requirements that are equal to, or substantially identical to, requirements imposed under federal law. *See, e.g., In re St. Jude Medical, Inc. Silzone Heart Valves Prods. Liab. Litig.*, No. MDL 01-1396, 2004 U.S. Dist. LEXIS 148, *1 (D. Minn. Jan. 5, 2004).

Thus, in addition to their arguments that preemption does not apply for purely legal reasons, Plaintiffs need discovery to set forth evidence in opposition to Medtronic's summary judgment motion that demonstrates a factual basis for their causes of actions that are not preempted. *See id.*; *Lohr v. Medtronic, Inc.*,

518 U.S. 470 (1996) (reversing dismissal of state-law negligent design, manufacturing and labeling claims as not preempted).[2]

Although Plaintiffs believe that manufacturing claims are not preempted as a matter of law, Plaintiffs seek the manufacturing documents requested (pertaining to returned devices and testing results) to respond to Medtronic's allegations that no manufacturing defect evidence exists. Thus, as a factual matter, Plaintiffs must compare documents related to what was manufactured with the design specifications approved by the FDA. Without this evidence, Plaintiffs' expert will be unable to show facts that demonstrate that the device failures were due to faulty manufacturing. If Plaintiffs are able to establish a manufacturing defect, Medtronic's preemption arguments fail as a matter of law.

As it stands, the Order unfairly prejudices Plaintiffs' ability to respond to Medtronic's summary judgment motion and is clearly erroneous and contrary to law. Plaintiffs, therefore, respectfully request that the portion of the Order denying Plaintiffs' motion to compel production of discovery about Medtronic's awareness of the recalled defibrillators' defects and risks, and whether the devices

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[2] To the extent that Medtronic failed to comply with federal regulatory requirements (such as failure to comply with the FDA's pre-market approval ("PMA") condition), its preemption defense fails. *See, e.g., In re St. Jude Med., Inc.*, 2004 U.S. Dist. LEXIS 148, *39 (D. Minn. Jan. 5, 2004) (acknowledging that "[t]he FDA can withdraw approval if the manufacturer has not met all post-approval requirements, if the device is unsafe or ineffective or if the PMA contained or was accompanied by an untrue statement of material fact.").

contain design or manufacturing defects (*i.e.*, Document Request Nos. 2, 8, and 36), be reversed.

ARGUMENT

District of Minnesota Local Rule 72.2(a) largely mirrors Fed. R. Civ. P. Rule 72(a) and provides, in pertinent part:

> Within 10 days after being served with a copy of the Magistrate Judge's order, unless a different time is prescribed by the Magistrate Judge or a District Judge, a party may serve and file objections to the order; a party may not thereafter assign as error a defect in the Magistrate Judge's order to which objection was not timely made.
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> The District Judge to whom the case is assigned shall consider such objections and shall modify or set aside any portion of the magistrate Judge's order found to be clearly erroneous or contrary to law. The District Judge may also reconsider any matter *sua sponte*.

In accordance with L. Civ. R. 72.2(a), Plaintiffs hereby object to the Order and ask that the Court reverse that portion of the Order that denies Plaintiffs' motion to compel production of discovery about Medtronic's awareness of the recalled[3] defibrillators' defects and risks, and whether the devices contain design and/or manufacturing defects (*i.e.*, Document Request Nos. 2, 8, and 36). *See* Affidavit of Karla M. Gluek dated April 7, 2006 ("Gluek Aff.") Ex. A. The Order

[3] Federal regulations state that "[r]ecall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, *e.g.*, seizure." 21 C.F.R. § 7.3(g).

is clearly erroneous and contrary to law because: (1) Plaintiffs must be able to present evidence that their claims are not preempted; and (2) preemption discovery properly includes evidence in support of non-preempted claims.

I. PLAINTIFFS MUST BE ABLE TO PRESENT EVIDENCE THAT THEIR CLAIMS ARE NOT PREEMPTED

In order to fairly oppose Medtronic's motion for summary judgment, Plaintiffs must be able to present evidence that their claims are not preempted. *See, e.g., In re St. Jude Med., Inc.,* 2004 U.S. Dist. LEXIS 148 (D. Minn. Jan. 5, 2004) (refusing to find plaintiffs' claims preempted, including *inter alia* claims for negligence, strict liability and design defects until after the completion of discovery and with a full evidentiary record); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 790 (8th Cir. 2001) (issuing preemption decision only *after* discovery was complete); *Woods v. Gliatech, Inc.*, 218 F. Supp. 2d 802, 806 (W.D. Va. 2002) (stating "The determination regarding the scope of an express preemption provision 'does not occur in a contextual vacuum'").

In *St. Jude*, an analogous case from this Court, defendant St. Jude, a manufacturer of a variety of medical devices including recalled prosthetic heart valves, argued that plaintiffs' state-law personal injury claims were preempted as a matter of law. *Id.* at *12. Plaintiffs, asserting FDA approval was improperly secured and unlawfully maintained, argued that their personal injury claims could not be preempted by the FDA's pre-market approval ("PMA") process. *Id.*

Despite *Buckman*,[4] which expressly did not overrule *Lohr*,[5] the Court held: (1) state or local requirements are preempted only when the FDA has established "specific counterpart regulations;" (2) state or local requirements of "general applicability" are not preempted; (3) state or local requirements that are "equal to, or substantially identical to," requirements imposed are not preempted; and (4) state or local requirements prohibiting the manufacture of "adulterated or misbranded" devices are not preempted. *Id.* at *25, *34 n. 11, *39, *52 (quoting pertinent FDA regulations).

The *St. Jude* Court made clear that summary judgment was only decided after development of a complete evidentiary record. *Id.* at *37, *46: "[P]laintiffs would have to establish that defendant knew of the particular risks during the PMA Supplement process, and that the risk [wa]s scientifically valid." *Id.* at *37.

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[4] The *St. Jude* Court analyzed *Buckman* at length and distinguished it from cases such as these which involve personal injuries and concluded, "Plaintiffs in Buckman made *only* "fraud on the FDA claims." *Id.* at *29-*33 (emphasis added). The *St. Jude* Court further disposed of defendant's attempts to expand the reach of *Buckman* and stated, "Defendant apparently would have the Court read *Buckman* so as to preempt any and all claims in which any inquiry into the FDA regulatory process is necessary." *Id.* at *43-*44. The *St. Jude* Court clearly rejected this argument and held that "with specific evidence," the plaintiffs properly "raised disputed issues of material fact such that their [personal injury] claims survive[d] summary judgment on the ground of preemption." *Id.* at *46.

[5] The *Buckman* Court rejected respondent's attempt to characterize both the claims at issue in *Lohr* (*i.e.*, common-law negligence) with the fraud-on-the-FDA claims at issue in *Buckman* and stated, "it is clear that the [*Lohr*] claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of [FDA] requirements." *Buckman*, 531 U.S. at 353.

Summary judgment was denied because plaintiffs obtained discovery and therefore could "point to specific facts in the record demonstrating a dispute of material fact." *Id.* at *37. The Court noted plaintiffs' persuasive pre-approval and post-approval evidence included:

- evidence that defendant misrepresented the results of animal tests to the FDA because defendant failed to report the death of one of the subject animals; and
- evidence of public reports from the medical community of high rates of stroke and other thromoembolic events, as well as allegedly high explant patterns.

Id. at *37 n.13. Plaintiffs in that case successfully argued that this evidence established knowledge on defendant's part that the device was problematic, yet defendant did not report the problems to the FDA. *Id.* The Court held, "to the extent that plaintiffs' negligence and defective design claims hinge on violations of FDA requirements, the claims are not preempted, and summary judgment is not appropriate." *Id.* at *39.

Plaintiffs in this case must similarly be allowed to present evidence that their claims are not preempted in opposition to summary judgment and that defendant was aware of the defects at issue (yet did not properly report the problems to the FDA), including manufacturing defects. To make this point,

Plaintiffs must necessarily obtain evidence of what the defects were.[6] The Order deciding the converse in this case is clearly erroneous and contrary to law.

II. PREEMPTION DISCOVERY PROPERLY INCLUDES EVIDENCE IN SUPPORT OF NON-PREEMPTED CLAIMS

The scope of preemption discovery includes evidence in support of non-preempted claims. *See, e.g., In re St. Jude Med., Inc.*, 2004 U.S. Dist. LEXIS 148, *37; *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788 (2005) (noting that in the early stages of litigation they could not "opine on whether petitioners can adduce sufficient evidence in support of their claims [against preemption] to survive summary judgment."). In other words, in order for Plaintiffs to oppose Medtronic's preemption claims, Plaintiffs must be able to show the existence of non-preempted tort law claims (such as manufacturing defects or state-law causes of action that parallel federal safety requirements).

Furthermore, as stated above, to the extent that Medtronic is not in compliance with federal regulatory requirements and PMA conditions, it's preemption defense will fail. *See, e.g., Brooks*, 273 F.3d at 790, 798 ("[A] claim of failure to comply with FDA regulations is not preempted by the MDA"); *Quillin v. Am. Hosp. Supply Corp.*, No. 94-C-1020-BU, 1997 U.S. Dist. LEXIS 6974, *14-*15 (N.D. Okla. Mar. 31, 1997) ("The fact that the premarket approval

[6] For example, *what* Medtronic knew in terms of field reports, failures, complaints and testing results are critical areas of inquiry since it is often the quality of the complaint and failure investigation testing that triggers reporting obligations.

process involves specific requirements must not be confused with the premarket approval requirement itself acting as a specific requirement.").

In Plaintiffs' Motion to Compel Discovery, filed on February 22, 2006, Plaintiffs articulated the reasons for each discovery request made to date and their relevance to federal preemption. *See* Gluek Aff. Ex. B. Oral argument on the issues was heard before the Magistrate Judge on March 9, 2006. *See* Gluek Supplemental Aff. dated April 11, 2006, Ex. C. On March 24, 2006, Magistrate Judge Boylan issued the Order to which Plaintiffs have now articulated very limited and specific objections. *See* Gluek Supp. Aff. Ex. D.

Among the documents requested from Medtronic, Plaintiffs seek customer and physician complaints, component rejections and returned devices. This evidence is critical to a preemption analysis because it will allow Plaintiffs to illustrate what defects Medtronic was aware of, and that it concealed risks (to the FDA and the public) relating to the devices in violation of state-law and parallel federal law.[7] *See* Gluek Aff. Ex. A.[8]

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[7] *See* 21 C.F.R. §§ 814, 820; 21 C.F.R. §§ 814.82(a)(9); 21 C.F.R. § 814.84 and 21 C.F.R. § 803 (requiring Medtronic to maintain data on adverse events, field and laboratory failures).

[8] It appears from the Order, that the Court was concerned that Plaintiffs were intending to use this information to look for clients. Although that is not Plaintiffs' intention, this concern can be entirely mitigated by redacting patient and physician identifying information.

In addition, it bears repeating that this Court has already ordered adverse event reports be produced at this juncture, which Medtronic steadfastly refuses to do.[9] *Id.* at p. 5. It is incongruous that Magistrate Judge Boylan has granted Plaintiffs discovery into "Alternative Summary Reporting" for adverse events (Document Request No. 7) and documents relating to when Medtronic first learned of device defects or risks, including battery depletion (Document Request No. 16), but denies Plaintiffs the right to documents in response to Document Request Nos. 2 and 8 (which would tell us what defects Medtronic actually knew about). Furthermore, in accordance with applicable law, Plaintiffs must be able to present evidence that the claims that underlie their need for the requested discovery are not preempted. *See, e.g., In re St. Jude Med., Inc.,* 2004 U.S. Dist. LEXIS 148, *39.[10]

With Document Request No. 36, Plaintiffs ask for evidence in support of design or manufacturing defect claims. *See* Gluek Aff. Ex. B. To the extent Medtronic argues that these claims are preempted, the evidence is critical to a preemption analysis because Plaintiffs will counter - if possible - that

[9] This Court's January 20, 2006 Pretrial Order specifically states permitted document requests for preemption discovery would include "All adverse event reporting documents regarding the devices at issue." *Id.* at p. 4.

[10] Indeed, Magistrate Judge Boylan seemed to recognize at argument that *St. Jude* carved out an exception to *Buckman*. *See* Gluek Aff. Ex. C, p. 22.

manufacturing defects existed in the relevant devices[11] and that these claims are not preempted (nor do they amount to fraud-on-the-FDA claims, as Medtronic contends). *See, e.g., Lohr v. Medtronic*, 518 U.S. 501-502 ("The legal duty that is the predicate for [plaintiffs'] negligent manufacturing claims is the general duty of every manufacturer to use due care to avoid foreseeable damages in its products."); *Bates v. Dow Agrosciences*, 125 S. Ct. at 1799 ("Rules that require manufacturers to design reasonably safe products, to use due care in conducting appropriate testing of their products, to market products free of manufacturing defects, and to honor their express warranties or other contractual commitments plainly do not qualify as requirements for 'labeling or packaging.'"); *Chielewski v. Stryker Sales Corp.*, 966 F. Supp. 839, 843 (D. Minn. 1997) ("Assuming that plaintiffs can show that this alleged processing defect violates FDA standards, their negligent manufacturing claim would not conflict with federal law and this would not be preempted.").

Plaintiffs in this case must be allowed to present evidence that their tort law personal injury claims are not preempted and, as in *St. Jude*, that Medtronic was aware of the defects at issue and yet did not properly report the problems to the FDA. The Order denying Document Request Nos. 2, 8 and 36 is clearly

[11] By "relevant devices," Plaintiffs do not seek documents related to the manufacture of all the recalled devices (87,000), but rather refer to devices that have been returned to Medtronic from the field and confirmed by testing to have experienced the shorting mechanism, as well as those identified by Medtronic in its accelerated laboratory testing.

erroneous, contrary to law and unfairly prejudices Plaintiffs' ability to respond to Medtronic's summary judgment motion.

CONCLUSION

For all the foregoing reasons, Plaintiffs respectfully request that the Court reverse the portion of the Order denying Plaintiffs' motion to compel production of discovery about Medtronic's awareness of the recalled defibrillators' defects and risks, and whether the devices contain design or manufacturing defects (*i.e.*, Document Request Nos. 2, 8, and 36).

Dated: April 11, 2006

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